K102830 P1/3

510（K）Summary of Safety and Effectiveness

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter:

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DEC 2 2010

Contact person:

Yue Qiuhong
Edan Instruments, Inc.

Date: 2010-9-25

Proprietary Name:

Electrocardiograph
models SE-12/SE-1200/SE-12Express/SE-1200Express

Classification Name:

21 CFR 870.2340 Electrocardiograph
Class II

Product code: DPS

Predicate Devices:

MAC 5000 ECG Analysis System K014108
Manufacturer: GE medical systems information technologies
SMART ECG SERIES ELECTROCARDIOGRAPH
K091513 Manufacturer: Edan Instruments, Inc

Device Description:

SE-12 series is 12-channel electrocardiograph, it contains four models:SE-12/SE-1200/SE-12Express/SE-1200Express. These four models include the same ECG board, power supply board and main controlling board. The software and function of these four models are similar, except that SE-12Express has the optional function which include stress exercise test. SE-12 series can acquire 12 channel waveforms simultaneously, which can also print out 12 channel

electrocardiograph wave simultaneously by a 216mm wide thermal printer, and the waveforms also can be displayed in LCD and stored in flash memory or send to PC by RS232 or Ethernet.

SE-12 series has the features as follows:

Supporting barcode scanner

Supporting multi-language

ECG signals of 12 leads are gathered and amplified simultaneously, 12-channel waves are displayed and recorded simultaneously

Full alphanumeric keyboard

(For SE-1200Express and SE-12Express, touch screen is available)

Real-time uploading to PC ECG

Multiple file formats

High resolution thermal recorder, recording frequency response ≤150Hz

Flexible printing formats

The auto, manual, rhythm, R-R analysis and off modes can be chosen freely

Automatic baseline adjustment for optimal printing

Convenient operation of system setup and file management

Measurement function and interpretation function

Hint information of lead off, lack of paper, low battery capacity etc.

Built-in rechargeable lithium battery with large capacity

ECG data can be transmitted to the PC software through the serial cable, net cable, or wireless AP (optional).

The following features are only for the exercise stress test function of SE-12 Express (optional)

Real-time analysis, ST segment and trend are applied while sampling;

Real-time display and print of 12-lead simultaneous ECG waveforms;

ST segment analysis while sampling; ST position is adjustable while sampling;

Providing average templates of three rhythm leads in every stage to observe the change of ST segments between every two stages

Automatically forming elaborate reports, including Summary

	Report, ST Scope Report and Trend Graph Report Providing classical exercise protocols; exercise protocols can be edited and created Automatically controlling and adjusting the speed and grade of the treadmill or the power of the bicycle Supporting multi-types of treadmill or bicycle
Intended Use:	The intended use of the SE-12 series (12-channel electrocardiograph) is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.
Test Summary:	The following quality assurance measures were applied to the development of the SE-12 series. • Software testing • Risk analysis • Safety testing • Environment test
Conclusion:	Verification and validation testing was done on SE-12 series. This premarket notification submission demonstrates that SE-12 series is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 2010

Edan Instruments, Inc.
c/o Ms. Yue Qiuhong
Registrar
3/F - B, Nanshan Medical Equipments Park, Nanhai Rd 1019#
Shekou, Nanshan Shenzhen, 518067
P.R. China

Re: K102830
Trade/Device Name: SE Series Electrocardiograph (Models SE-12, SE-1200, SE12Express, SE-1200Express)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: October 28, 2010
Received: November 8, 2010

Dear Ms. Qiuhong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

DEC 2 2010

510(k) Number (if known): K102830

Device Name: Electrocardiograph models SE-12/SE-1200/SE-12Express/SE-1200Express

SE-12 series is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. SE-12 series is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-12 series can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

Prescription Use ___X___ Or Over the Counter Use _____.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102830